MEDICATION REFILLING SYSTEM BY USING HL7 STANDARD IN THAILAND: A NEW POLICY CHALLENGE

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ABSTRACT

Chronic diseases are common health problem in Thailand. In general, chronic disease patients have followed up with physicians. The physicians have usually prescribed the repeated medications, when their clinical treatment results are stable. With an online database accessibility of collaborative health information between hospitals and pharmacy stores, the process of repeat medication without physician appointment, namely medication refilling, is not taken in to account a Thailand's standard policy, and its health information is also limited for access. To develop a policy for implementation of medication refilling system, the Health Level-7 (HL7), the most widely accepted standard for electronic health information exchange, is proposed. With an improved policy under development of HL7 on medication refilling system, most of stakeholders agree and satisfy with this policy and expect the policy should be implemented.

KEY WORDS: Health Level-7 / HL7 / MEDICATION REFILL / PRESCRIPTION REFILL

51 pages

นโยบายระบบการเติมยาในประเทศไทยโดยมาตรฐาน H L7
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บทคัดย่อ

โรคเรื้อรังเป็นปัญหาด้านสุขภาพที่สำคัญของประเทศไทย ผู้ป่วยโรคเรื้อรังเหล่านี้ต้องได้รับการรักษาด้วยยาและตรวจติดตามโดยแพทย์อย่างสม่ำเสมอ และในกรณีที่ผู้ป่วยมีอาการทางคลินิกคงที่นั้น แพทย์มักจะสั่งจ่ายยาด้วยรายการยาเดิม ซึ่งกระบวนการที่ผู้ป่วยโรคเรื้อรังสามารถรับยาเดิมโดยไม่จำเป็นต้องพบแพทย์นั้น เรียกว่า “ระบบเติมยา” สำหรับประเทศไทยนั้นยังไม่มีนโยบายเกี่ยวกับระบบเติมยาอย่างเป็นมาตรฐาน ดังนั้นหากมีการนำระบบเทคโนโลยีสารสนเทศทางการแพทย์เข้ามาประยุกต์ในใช้การส่งข้อมูลระหว่างโรงพยาบาลและร้านยา จะสามารถเพิ่มความสะดวกให้แก่ผู้ป่วยที่จะเข้ารับบริการการเติมยาที่ร้านยาได้ และยังเพิ่มประสิทธิภาพการเข้าถึงข้อมูลสารสนเทศทางการแพทย์ได้ จึงเป็นที่มาของจุดประสงค์ของงานวิจัยนี้ คือ เพื่อนำเอามาตรฐานของระบบสารสนเทศทางการแพทย์มาประยุกต์ใช้กับนโยบายระบบเติมยา เพื่อให้เกิดระบบการส่งข้อมูลที่มีมาตรฐาน และลดข้อจำกัดในการเข้าถึงข้อมูล ไปจนเพิ่มคุณภาพในการให้บริการการเติมยา ซึ่งมาตรฐานที่ได้รับการยอมรับอย่างมากในระดับสากล คือ Health level 7 (HL7) เมื่อนำเอามาตรฐาน HL7 นำมาทดลองใช้กับนโยบายระบบเติมยา พบว่าเพิ่มคุณภาพในการบริการและการส่งข้อมูลระหว่างโรงพยาบาลและร้านยาได้ จากผลจากการสำรวจพบว่า ผู้มีส่วนเกี่ยวข้องทั้งแพทย์ เภสัชกรและผู้ป่วยให้การยอมรับและความพึงพอใจต่อนโยบายนี้ และสนับสนุนให้มีการนำนโยบายระบบการเติมยาไปใช้จริง

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LIST OF ABBREVIATIONS

ANSI	American National Standards Institute
API	Application Programming Interface
ASCII	American Standard Code for Information Interchange
CCOW	Context Management Specification
CDA	Clinical Document Architecture
DICOM	Digital Imaging and Communication in Medicine
ebXML	Electronic Business Extensible Markup Language
EMR	Electronic Medical Records
EPR	Electronic Patient Records
FDA	Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
GPO	Government Pharmaceutical Organization
HIS	Hospital Information System
HL7	Health Level Seven International
HN	Hospital Number
HTTP	Hypertext Transfer Protocol
HTTPS	Hypertext Transfer Protocol Secure
ICD	The International Classification of Diseases
ID	Identification number
JSON	JavaScript Object Notation
MIME	Multi-Purpose Internet Mail Extensions
NHSO	National Health Security Office
PRIS	Prescription-release information system
RIM	Reference Information Model
SD	Standard Deviation
SDMP	The Separation of dispensing from the medical practice
SMTP	Simple Mail Transfer Protocol

LIST OF ABBREVIATIONS (cont.)

TCP/IP	Transmission Control Protocol/Internet Protocol
THB	Thai Baht
VMI	Vendor Managed Inventory
VPN	Virtual Private Network
XML	Extensible Markup Language

CHAPTER I
INTRODUCTION

Chronic disease defines as persistent conditions that can be controlled but not cured. Examples of chronic diseases included the heart diseases, diabetes, chronic kidney diseases, asthma, and so on. Managements of chronic disease are life style modification and medication treatment. The common characteristics of chronic disease patients are prescribed a lot of medications and monitored by physician for their lifelong [1], [2].

1.1 Background

Chronic diseases are common health problem and major cause of death in Thailand [3]. The number of newly diagnostic chronic disease patients has dramatically increased up to one million since 2012 [4]. Most patients, suffering from chronic diseases, need numerous medications for treatment. With frequent physician's follow-up, the patients are dispensed multiple medications while most of their prescriptions are repeated. This process is called *"medication refilling"*. Definition of medication refilling system is system that allows to refill prescription a few times without returning to see their physicians [5].

Due to frequent hospital visits, the patients take the high effort for transportation cost and waiting time for medication. These are reasons why some patients prefer to buy their medication at pharmacy store nearing their home, and loss the physician's follow-up. For this concern, with unknown patient's medication profile for pharmacy store, the patients usually go to pharmacy store without any prescription, leading to harmful for patients from inconsistent treatments. Hence, medical information including medication name, dose, frequency, and route of administration becomes important information for medication refilling.

At present, in Thailand, an accessibility of medical information is difficult with permission access and is no standard for health informatics system. Some facilities still use legacy system. To overcome the problem, the proposed solution is to build an interoperable system, connecting among healthcare facilities (hospital, clinic and pharmacy store), for medication refilling by implementation of healthcare standard. Then, patients would receive their medications at the preferred location facilities. This would make medication service more convenient/compliance and cost/time saving, leading to successfully treatment.

Nowadays, there are many standards for healthcare communication standards. The most widely accepted international electronic communication standard issuing protocols is Health Level Seven International (HL7). HL7, developed by the non-profit organization of American National Standards Institute (ANSI), is proposed for exchange, integration, sharing, and retrieval for electronic health information. In addition, HL7 supports the clinical practice and management including delivery and evaluation for health services [6].

1.2 Objectives

To design the policy of medication refilling system with HL7 standard and demonstrate the implementation of HL7 standard for sharing medication information among healthcare facilities in Thailand.

To measure the medication refilling policy satisfaction and stakeholder's perspective by survey method.

1.3 Scope of work

This study focuses on designing of medication refilling system and policy base on HL7 standard. The system design is relevant to data and information, and creates electronic health information communication method. The study is not application development. Policy of medication refilling system and key stakeholders will be clarified. Expected benefits of system will be discussed. Outcomes of this

study are medication refill policy, heath informatics exchanging process, and policy satisfaction.

1.4 Expected result

Medication refilling system and policy are designed and built interoperable communication system among facilities. Prescription information and related patients information could be shared between healthcare facilities. The medication refilling system is effective and efficient to implementation. The key stakeholders accept and satisfy the policy and system.

1.5 Processes of work

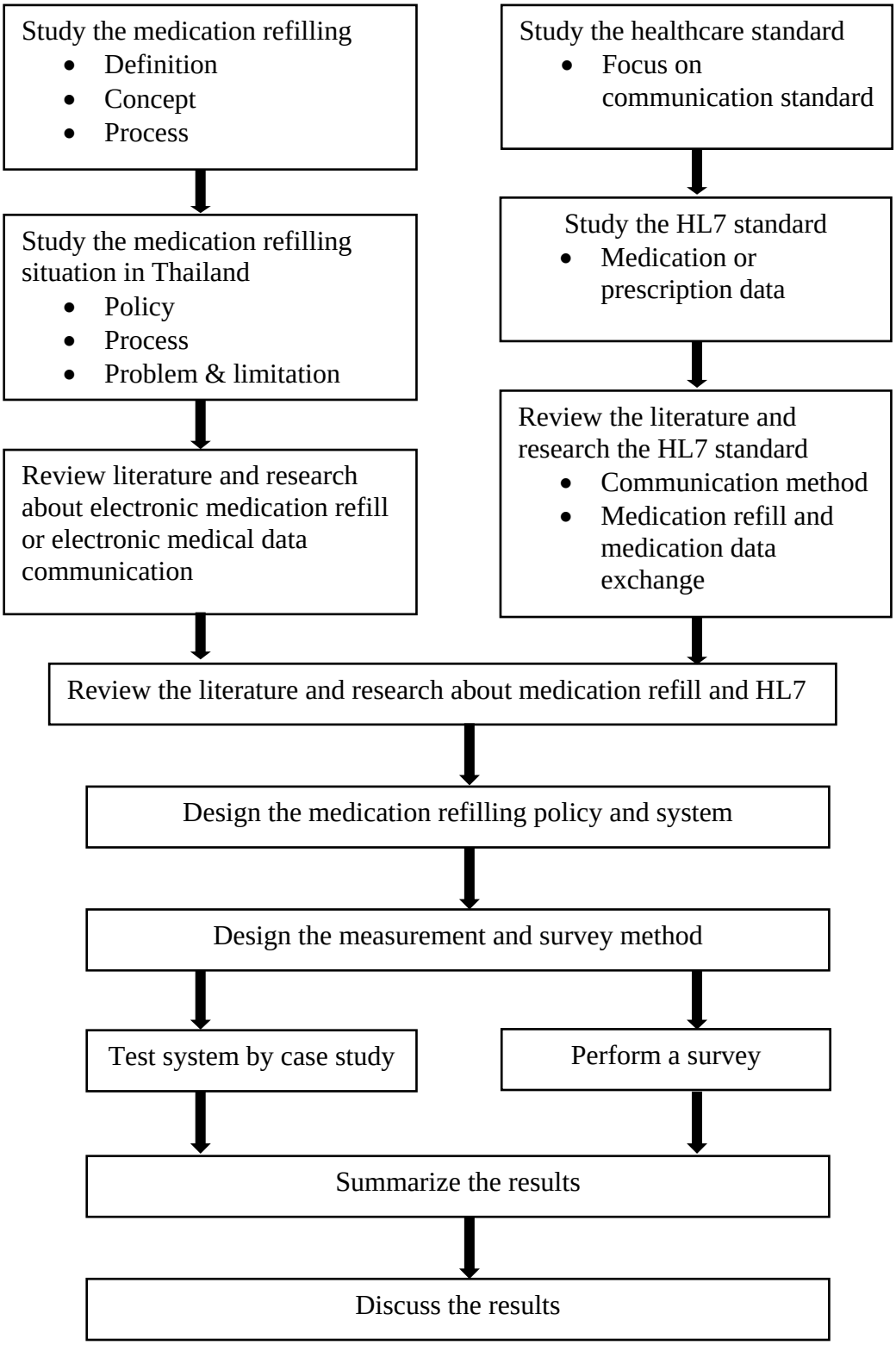

Figure 1.1 The processes of work

CHAPTER II
REVIEW LITERATURE

2.1 Healthcare standard

Healthcare standards are developed to improve the quality and performance in healthcare service. The standards like the guideline to assure the service to meet the best practice. Healthcare standard aims on patient or service. Nowadays, there are many kinds of healthcare standards implemented.

We focus on the communication standard, because our objective is to create standard for sharing the medication information among the healthcare facilities.

Patient's documents can record on paper or electronically. Electronic medical records (EMR) or electronic patient records (EPR) are the tool for improving the patient care service and increasing the patient safety. EMR contains the patient's medical history within one health care organization but the data unable shared to others. To enhance the capability of information use and to eliminate boundaries between facilities, healthcare standards are adopted [7].

Healthcare standard concerns in privacy, security, electronic use of information, and electronic communication in healthcare. There are many healthcare standards, which have been used for different purposes. Examples of healthcare standard are given as: digital imaging and communication in medicine (DICOM) for medical imaging domain, ISO/IEEE 11073 for medical device communication, ICD-9 for diseases classification, and HL7 for transfer of clinical data between hospital information systems (HIS). The principal of HIS is data completion, real time, and accuracy. The accuracy includes internal and external system to integrate. Healthcare standards deliver healthcare information. Standards for sharing or exchanging health information between healthcare facilities are relevant to interoperability, maintaining privacy and security of data [8].

Interoperability means the ability of health information systems to work together within and across organizational boundaries in order to improve the effective delivery of healthcare for individuals and communities [9].

Improving interoperability is benefit for healthcare providers, leading to efficiency and effectiveness healthcare system [7]. Standard implementation is challenge. Implementation of healthcare standard depends on content of healthcare information in system that uses for data processing. The frameworks must align to standard, regulation, internal policy, national policy, and governance. Understanding requirements of stakeholders is another key of successfully implementation [8].

2.2 Health Level 7 (HL7)

HL7 standard is widely accepted and adopted by several organizations in US department. HL7 is standards for exchanging health-related information among different systems. The goal of HL7 is interoperability. Hospital and other healthcare facilities have various EMR formats. Interoperability includes in HL7 supports the clinical practice, management, and healthcare services. HL7 covers all specification of healthcare domains as follows: patient care, patient administration, pharmacy, medication order, public health, and financial management. HL7 is divided into many categories that cover the implementation of guidance [6].

HL7 develops the document standards (e.g., Clinical Document Architecture; CDA), standard for application programming, runtime environment infrastructure (e.g., Context Management Specification; CCOW), and messaging standards (e.g., HL7 version 2, version 3). Messaging standards are important, because there are message format, structure and data types for integration form system to another to achieve interoperability. [6]

2.2.1 Message and document

Messaging and document standard are also grouped in clinical and administrative domains. This section is supported the clinical specialties such as the clinical statement, patient referral, medical record, laboratory, pharmacy, and so on [10].

Clinical document standard (CDA) supports the exchange of clinical documents between healthcare providers in patient care purpose. Common types of clinical documents are discharge summary, admission report, imaging report, pathology report, etc. CDA is a part of HL7 version 3. The concept of CDA is incremental semantic interoperability. The CDA uses XML-encoded for metadata, which includes the patient information, provider name, type of documents and document identifier. MIME (Multi-Purpose Internet Mail Extensions) type is used for body content. MIME developed from Internet e-mail protocol allows exchanging the different kinds of data files. Text file or images file can be attached on the clinical documents. One of documents characteristic is persistence, describing the clinical occurrence is done at a specific time. Clinical document is not real time, the passive communication. Examples of CDA's application are patient referral, discharge summary, and diagnostic report [11].

2.2.2 Messaging standard

Messages are created when trigger events or requests are occurred and send to the receivers. Messages will deliver the current and update available information. Capability of messages is real-time or near real-time information that supports the ongoing process in system. Messages are appropriated for active communication [12].

Messaging is designed to support a patient care system, and allows exchanging clinical data between systems. HL7 version 2 uses a human-readable (American Standard Code for Information Interchange; ASCII), and non-XML (Extensible Markup Language; XML) encoding syntax [6]. Example of HL7 version 2 messages are shown in Figure 2.2. HL7 version 3 is developed, because of the problems of version 2 including lack of consistency data model, informal methodologies, ambiguous definition, unclear roles, and vagueness. HL7 Version 3 is to create the explicit data model, clear definition, and more use cases in message elements. Specifications of HL7 version 3 are based on Reference Information Model (RIM) of the health care information domain. RIM provides the formal version 3 methodologies include data type model, the message life cycle, set of vocabulary, and messaging architecture for sharing healthcare information by using document [13]. The core concepts of RIM are shown in Figure 2.1. These methodologies of version 3 have been also adopted by ISO (ISO 21090). HL7 version 3 messages syntax are served by XML encoding methods. Examples of HL7 version 3 messages are shown in Figure 2.3. Transportation specifications include ebXML (Electronic Business XML) that contains reliable messaging, encryption, authentication and digital signatures. Message transportation can use over lower level transports such as HTTP, SMTP, and TCP/IP [6], [14-15].

Table 2.1 Comparisons between HL7 documents and messages.

Topics	**HL7 CDA**	**HL7 Message**
Communication	Passive	Active
Model	Static	Dynamic
Information status	Persistent	Current /real time
Human readability	Yes	Yes
Encoding	XML and MIME	V2: ASCII & non-XML V3: XML
Other files attachable	Yes	No
Example of Applications	Patient referral Discharge summary	Medication order Laboratory order

Table 2.2 Difference between HL7 version 2 and version 3 messages.

Topics	Version 2	Version 3
Interoperability specification	Yes	Yes
Framework for negotiation	Most	Less
Consistency	No	Yes
Compatibility with Version 2.x	Yes	No
Standard	Messaging-based	Model-based (RIM)
Application roles define	No	Yes
Encoding syntax	Non-XML	XML

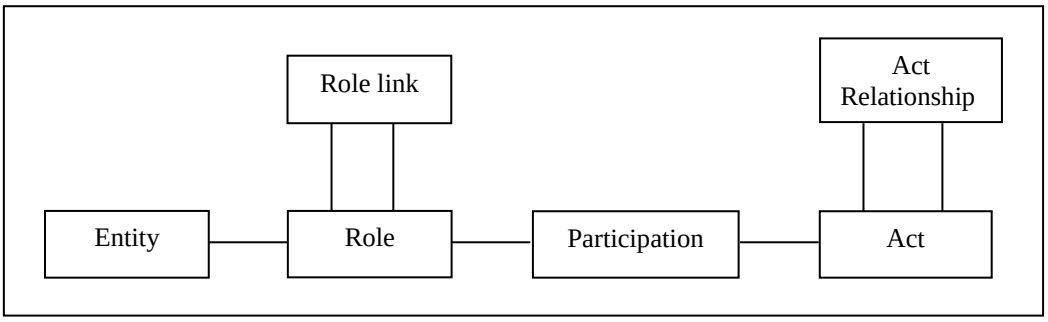

Figure 2.1 The reference information model (RIM) [13].

Table 2.3 RIM core concepts and definitions [13].

RIM concepts	Description	Example
Act	The things that happening	procedures, observations, monitoring, medications, medical supply
ActRelationship	Relationship of Act	composition, preconditions, revisions, support
Participation	The context for Act	author, performer, subject, location
Role	Role of the participants	patients, provider, practitioner, staff
Entities	Entities play roles	organizations, persons, material, places, devices

```
MSH | ^ ~\& | HIS | MedHosp|20060315496361|ADT^A05|MSGID20060315496361|P|2.4
EVN |A05
PID | | |5736043| |Dang^Green | | 22011905 | M | | | 100 First road.^^ Bangkok^BKK^10700^Thailand
PV1 | | O | OP^PAREG^ | | | | 1235^ Bang^Green | | | OP | | | | | | | | | | | | | | | | | | | | | | | 20060315496361
AL1 | 1| | 3123^aspirin | | Maculopapular~Rash
```

Figure 2.2 Example of HL7 Version 2 message.

```
<author>
<assignedEntity>
        <id root=”2.17.840.1.114855.8945.210.3”
        Extension=”5473610”
        <telecom value=”tel:+44(187)675-5555” />
<assigneePerson>
<name>
        <given>Dang</given>
        <family>Green</family>
        <suffix>MR</suffix>
</name>
</assigneePerson>
</assignedEntity>
</author>
<patientSubject>
<patient>
        <id root=<id root=”2.17.840.1.114855.8945.210.111”
        extension=”345533225”/>
<addr>
<telecom value=”tel:213-555-3456” />
<patientPerson>
        <id root=<id root=”2.17.840.1.24658.8855.5.1”
        extension=”345533225”/>
<name>
        <given>Sam</given>
        <family>Johns</family>
</name>
</patientPerson>
</patient>
```

Figure 2.3 Example of HL7 Version 3 message.

2.2.3 FHIR (Fast Healthcare Interoperability Resources)

FHIR is the latest standards framework for implementation purposes and development under HL7. The disadvantage of the previous standard (HL7 version 3 and RIM) is difficult to implement. FHIR is to simplify implementation, and provides flexibility, and manageable resources. FHIR provides human-readability and shows

the best practice governance. Benefit of FHIR specifications is free without restrictions. FHIR combines the features of HL7 version 2, version 3 and CDA. FHIR does not include all of HL7 version 3 resources and data type elements, but FHIR cover the most of them. FHIR has the built-in mechanisms, which is able to track RIM and other important content models. FHIR uses the web-based suite of API (Application Programming Interface) technology including HTTP-based, RESTful protocol, HTML, and CSS (Cascading Style Sheets) for user interface integration. FHIR creates seamless information exchanging message and document. Document formats of FHIR are given as XML and JSON. The XML notation is shown in Figure 2.4.

```
<Name xmlns="http://hl7.org/fhir" (attrA="value")>
      <nameA><!-- 1..1 type description of content  --><nameA>
      <nameB[x]><!-- 0..1 type1|type2 description  --></nameB>
      <nameC> <!--  1..* -->
            <nameD><!-- 1..1 type>Relevant records  --></nameD>
  </nameC>
</name>
```

Figure 2.4 The XML syntax form FHIR's resource [17].

FHIR provides *MedicationPrescription* resource for medication orders. This resource includes in-patient medication orders, community orders, and the refill prescription. The schema of resource is shown in Figure 2.5.

```
<MedicationPrescription xmlns="http://hl7.org/fhir">
 <!-- from Resource: extension, modifierExtension, language, text, and contained -->
 <identifier><!-- 0..* Identifier External identifier --></identifier>
 <dateWritten value="[dateTime]"/><!-- 0..1 When prescription was authorized -->
 <status value="[code]"/><!-- 0..1 active | on hold | completed | entered in error | stopped |
superceded -->
 <patient><!-- 0..1 Resource(Patient) Who prescription is for --></patient>
 <prescriber><!-- 0..1 Resource(Practitioner) Who ordered the medication(s) --></prescriber>
 <encounter><!-- 0..1 Resource(Encounter) Created during encounter / admission / stay --
></encounter>
 <reason[x]><!-- 0..1 CodeableConcept|Resource(Condition)
    Reason or indication for writing the prescription --></reason[x]>
 <medication><!-- 0..1 Resource(Medication) Medication to be taken --></medication>
 <dosageInstruction>  <!-- 0..* How medication should be taken -->
  <text value="[string]"/><!-- 0..1 Dosage instructions expressed as text -->
  <additionalInstructions><!-- 0..1 CodeableConcept
     Supplemental instructions - e.g. "with meals" --></additionalInstructions>
  <timing[x]><!-- 0..1 dateTime|Period|Schedule When medication should be administered --
></timing[x]>
  <asNeeded[x]><!-- 0..1 boolean|CodeableConcept Take "as needed" f(or x) --
></asNeeded[x]>
  <site><!-- 0..1 CodeableConcept Body site to administer to --></site>
  <route><!-- 0..1 CodeableConcept How drug should enter body --></route>
  <method><!-- 0..1 CodeableConcept Technique for administering medication --></method>
  <doseQuantity><!-- 0..1 Quantity Amount of medication per dose --></doseQuantity>
  <rate><!-- 0..1 Ratio Amount of medication per unit of time --></rate>
  <maxDosePerPeriod><!-- 0..1 Ratio Upper limit on medication per unit of time --
></maxDosePerPeriod>
 </dosageInstruction>
 <dispense>  <!-- 0..1 Medication supply authorization -->
  <medication><!-- 0..1 Resource(Medication) Product to be supplied --></medication>
  <validityPeriod><!-- 0..1 Period Time period supply is authorized for --></validityPeriod>
  <numberOfRepeatsAllowed value="[integer]"/><!-- 0..1 # of refills authorized -->
  <quantity><!-- 0..1 Quantity Amount of medication to supply per dispense --></quantity>
  <expectedSupplyDuration><!-- 0..1 Duration Days supply per dispense --
></expectedSupplyDuration>
```

Figure 2.5 The schema of *MedicationPrescription* resource [18].

When event occurs, a request message is sent from original destination to the terminal destination. RESTful API detects the supported resources (as interactions), then the information exchange between client and server by using a conformance statement.

FHIR is not secured protocol. FHIR is just exchange protocol and content model which requires secured protocol. HTTPS may be an option for communication. Authentication, access control and other security issues must be concern [16].

2.3 Medication refilling

Medication refill, also called prescription refill, is a protocol that pharmacists have authority to refill the chronic medications for patient without physicians' visiting. The benefits of medication refill protocol is improving the medical service, increasing convenience, decreasing errors associated with lately treatment [17].

Reige et al. [20] evaluated a refill clinic model. The Pharmacy Refill Clinics Pilot Study was developed for "standard package" for refill authorization program. The project determined the patient safety issues, cost savings, providers time saving, documentation issues, and the increased the patients benefits. The pharmacy refill clinic at the U.S. Naval Hospital at Keflavik, Iceland, adopted the pilot project model. The designed protocols were to provide the safe continuity of prescribing for stable patients. These protocols ensured patient safety and physician known how pharmacists should do in given situation. Pharmacist's roles were the patient's medical record reviewing, laboratory values monitoring, prescription refill history reviewing, and giving patient education for minimizing adverse side effects. It was found that pharmacists could effectively monitor drug therapy and confirmed cost saving and physician's time saving were benefits. Refill clinic's workflows were described as follows: First, the patients enrolled to the program; Seconds, the pharmacists reviewed and verified medication profile; Thirds pharmacist evaluated the laboratory value, and then authorized the refill, and the last copy information to providers. The workflow shows in Figure 2.6. If pharmacists found problems, pharmacists would forward to providers in every processes.

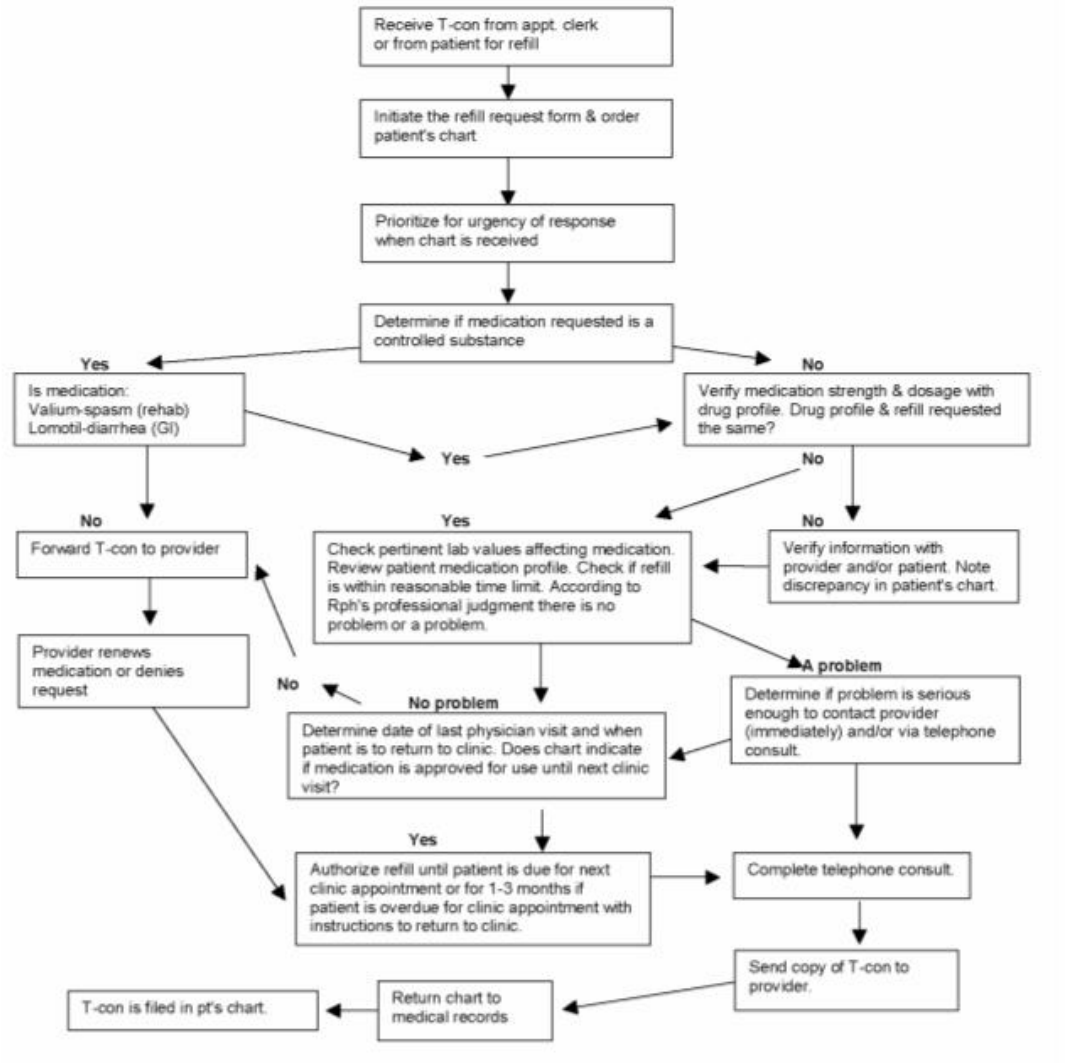

Figure 2.6 The pharmacy clinic work flow chart [20].

(T-con means Telephone consult with a nurse for initiate refill request)

Ferrell et al. [21] studied the effective and efficient process for prescription refill management by using best practices research method in primary care. Refill process consisted of 1) patient access to the process, 2) communication between pharmacy and physicians, 3) making a decision by clinical stuff, 4) patient notification, and 5) medical record documentation. It was found that a good refill management process required the accuracy, efficiency, acceptability and, applicability. Patients' satisfactions should be measured and concerned. The survey method with 5-point Likert scale questionnaires was used. The recommendation was patients should contact pharmacy first to request refill prescription. Efficiency involved cost and time issues. Decision-making should be performed by physicians to improve accuracy but

decision-making by nurses or assistants could reduce the cost. In patient notification process, pharmacist should inform and explain, if refill prescription had problem. Handwriting documentation probably made error and caused less satisfaction. Patients need complete and accuracy information. Electronic medical record system made documentation process with more efficient.

2.3.1 Controlled substances refills

Controlled substances are drugs that are regulated by state and federal laws that is to control the danger of addiction, abuse, physical and mental harm, the trafficking by illegal means, and the dangers from actions of those who have used the substances. Such drugs may be declared the illegal for sale or use, but may be dispensed under a physician's prescription. Examples of controlled substances are given as, opioid derivative for pain controlled pills, benzodiazepine for sleeping pills or anxiety symptoms, methylphenidate for attention deficit hyperactivity disorder, etc. [22], [23].

There were many concerns about controlled substance refills prescription, because of potential to abuse or dependence. The suggestions were depended on the laws and regulation. Management was hard to handle. Physician should control prescriptions. Patients must be carefully monitored for harmful or toxicity [23], [24].

Willis et al. 2010 [24] suggested the criteria of controlled substances refills to pain the controlled medications with fixed amount. The patients had well-controlled pain symptoms. The monthly medication refill was a predictable event.

Thai’s Food and Drug Administration (FDA) has the law to control some medication with the high risks for addictions or serious effects on mental status. FDA does not allow the pharmacy store to sale the psychotropic substances and the narcotics drug without prescription. To sale the medications abused on needs, the pharmacy stores must request the permission from FDA, and routinely summit the sale report to FDA.

2.4 The prescription-release information system in Taiwan

Taiwan [5] promoted the policy of the separation of dispensing from the medical practice (SDMP). The purposes were to protect the patient with medical safety and to provide the convenience for outpatients, especially for the patients in remote districts. SDMP allowed patients to refill their prescription at any convenient pharmacy. Failure of pharmacy to handle the refill prescriptions system was the inventory management especially for uncommon, expensive and controlled drugs. Prescription-release information system (PRIS) was developed to solve this problem. Target group was a chronic outpatient. Policy allowed the patient to choose the preferable contracted pharmacy. PRIS was designed to retrieve the prescriptions from the Hospital Information System (HIS) and transferred data to the terminal computer. The terminal computer located in the contracted pharmacy. The information on prescription included name, registration number of the medical record, clinical visit date, and the specialty. The complete medical records were saved in the database. XML was used for file transfer protocol. Communication between server and terminal must be secured. Virtual private network (VPN) was appropriate for secured and confidential patient profile. VPN provided the authentication between server and terminal. System reminded the pharmacist to notify patient for one week before appointment date, and the pharmacy could prepare the stock in advance.

The success factors of PRIS could be explained, given as:

1) System quality measured the reliability, accessibility, timeliness and security;

2) Information quality referred to completeness and accuracy on needed;

3) Service quality included the responsiveness, assurance, and empathy of staffs;

4) User satisfaction measured the accessibility, patient education and communication between patient and healthcare staff.

Waiting time and travelling time were indicated in accessibility. Patient education performed by healthcare staff to give medical knowledge and information. The questionnaires for measuring success factors were developed. Five experts validated the questionnaire. It found that the chronic outpatients were satisfied with the

SDMP policy with PRIS. Information quality showed a stronger effect on policy satisfaction than service quality and system quality.

It was suggested that the government should fully support for promoting, management, and supply chain service. Clearly explanation about reason and benefits of policy should be done. The image of pharmacists should be professional to ensure a quality service. Goal of healthcare policy must be clarified. Both physicians and pharmacists should agree the governmental objectives.

2.5 Medication refills services in Thailand

The pharmacists working at the governance hospital have the overload work. Therefore the Food and Drug Administration (FDA) and the Health insurance of Thailand have the policy to promote the pharmacy stores into health insurance system. At that time, Thai pharmacy council needed to improve quality of drug stores, and then the accredited pharmacy stores are integrated into health insurance system by medication refills service [25].

Pharmacy store made a sub-contract with the governance hospital to handle medication refills service. The refills service covered especially for some chronic diseases, such as diabetes mellitus, hypertension, and dyslipidemia. The result of this policy had shown the comparable clinical outcome between the patient with medication refills service and conservative treatment (only physician handles the treatment). Most of patient satisfied the medication refills service by accrediting the pharmacy store. Pharmacist reduced and prevented the drug related problem, leading to improve the rational use of drug. Hospital pharmacists found that the service could share the workload from hospital, and promoted working as multidisciplinary team. Medication refills service reduced overall healthcare expenditures [26].

In agreement of the results, National Health security Office of Thailand (NHSO) supports the accredited pharmacy to perform the medication refill services in chronic diseases.

2.5.1 Accredited pharmacy

Pharmacy stores are easily accessible and convenient for Thai patients having the common illness. Thai Pharmacy council has initiated the accredited pharmacy project since 2002. Standard of Drugstores are developed. Goals of the accredited pharmacy are to provide product service and the information service to encourage the rational drug use in community. The accredited pharmacy could help to improve the healthcare standard quality, leading to the high quality of life and healthy community. The standards control quality in 3 major topics given as the pharmaceutical care service, medical product/equipment and place. Register pharmacists must perform the service and control the quality to meet the standard. The pharmacy stores, certified by pharmacy council as the accredited pharmacy, could ensure the overall quality of pharmaceutical service [27].

CHAPTER III
METHODS

According to the literature review, we develop the method which divided into 7 steps as follows: The first step is the analysis of existing medication refilling service in Thailand. Second step is the creation of electronic information communication method based on Health Level 7 (HL7). Third step is the design of medication refilling policy and information system. Defining key stakeholders is the fourth step. After completion of system design, we test the medication refilling system with the case study. Sixth step is development of cost/time savings formulation scheme to prove our assumption. The last step is design the measurement of stakeholder's perspective and overall policy satisfaction by the survey questionnaires.

3.1 Analysis of the existing medication refill service in Thailand

Medication refill service has been performed in some hospital and has been restricted with the limited facilities. According to the pharmacy store, it is easier to access than hospital, and is necessary to improve the pharmacy's competency. The pharmacy council of Thailand qualifies some pharmacy store with good pharmacy practice and ensures the quality of pharmaceutical care service by the registered pharmacists. Thailand health system has been implemented the integration of the accredited pharmacy and health insurance. The medication refill clinic is a part of this policy.

The strength is the collaboration of National Health security Office of Thailand (NHSO) and pharmacy council of Thailand. NHSO supports the accredited pharmacy to handle the refill services [11]. Pharmacists, the medication experts, provide the effective pharmaceutical care and drug monitoring in the refilling clinic. Besides, working as multidisciplinary team, including physicians, nurses, pharmacists, and other healthcare workers, result in the successful refilling service. The weaknesses

are the limitation of information accessibility and data fragmentation. These are difficult to communicate/share information among healthcare facilities. Each of facilities have own information patterns and usually different from others. There is no health informatics technology for medication refilling system. Paper-based documentation has been used for communication between hospital and pharmacy. Implementation of HL7 is the opportunity to create the seamless communication. Using HL7 standard enhances the service's values. The threats are patient's perspectives. If patients do not clearly understand the purpose of medication refilling service, the patients may loss of the treatment care of physician. The most concerning issue is patient's unawareness. The pharmacists must clearly educate the patients for medication refilling system.

3.2 Health Level 7 (HL7) for medication refilling system

We adopt the messaging concept of HL7 Version 3 for our study and, demonstrate the implementation by Fast Healthcare Interoperability Resources (FHIR). We use HL7 messages for medication refilling system, because the messaging concept is the real time fashion. Medication orders maybe change or update if the problem is found by pharmacist. The Pharmacists can directly contact the physicians via medication refill network. This feature is proposed for next phase. In this study, we expect only exchangeable information.

HL7 is the standard for exchanging the health-related information among the different systems. Hospital and other healthcare facilities have various electronic medical record (EMR) formats. HL7 provides the messaging format, the structure, and the data types for integration form system to another. HL7 version 3 (HL7 V3) is messaging standard, and serves XML (Extensible Markup Language) as the message syntax and encoding methods [6]. HL7 messages are allowed to transmit on network between client and server [14 - 15]. The low level transport protocols as HTTP is used as the communication of HL7 messaging [6]. The data flow and its communication are shown as Figure 3.1.

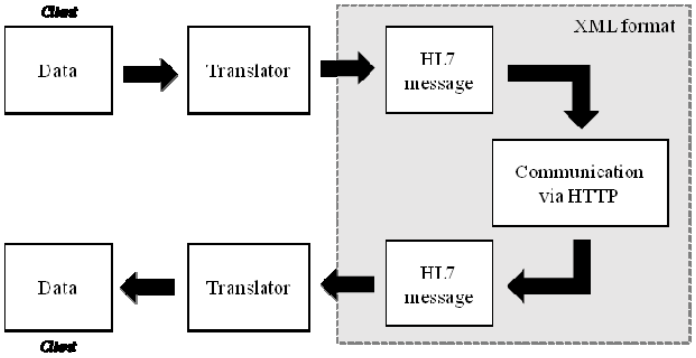

Figure 3.1 Data flow and communication.

FHIR (Fast Healthcare Interoperability Resources) is the standard framework for implementation purposes and development under HL7. HL7 FHIR provides simplicity, flexibility, and manageable resources. FHIR has been developed together with the testing server for the implementer with learning purpose. Formats of FHIR are given as XML and JSON. HL7 V3 methodology and code system, supporting the HTTP, are also included in FHIR [16].

Therefore, we created patient data and medication database for the case study by using FHIR resources [18]. We post the data to FHIR's testing server (*http://spark.furore.com/fhir)* with RESTful framework. Illustration of the case study database is shown in figure 3.2. The patient data are divided into demographic data and prescription profile. We assign the demographic data to storage in Hospital Information System (HIS). Prescription data are inputted to HIS when trigger event is occurred. The method of data creation will be described in the case study. Figure 3.3 shows patient information from FHIR's testing server in XML format. Medication resources are shown in Figure 3.4. The medication information in XML is demonstrated in Figure 3.5.

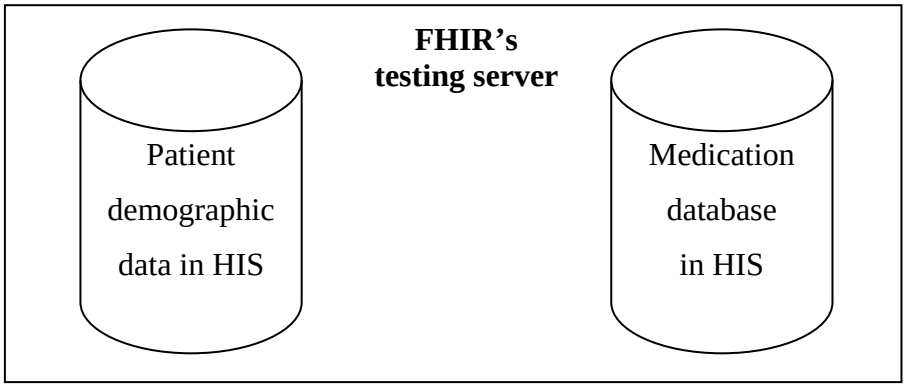

Figure 3.2 Database for case study.

```xml
<Patient xmlns="http://hl7.org/fhir">
  <name>
    <text value="AB" />
    <family value="BFamily1" />
    <given value="A" />
  </name>
  <telecom>
    <system value="phone" />
    <value value="123-555-2020" />
    <use value="work" />
  </telecom>
  <gender>
    <coding>
      <system value="v3/AdministrativeGender" />
      <code value="M" />
      <display value="Male" />
    </coding>
  </gender>
  <birthDate value="1950-02-01" />
  <address>
    <use value="home" />
    <line value="121 Home Street" />
  </address>
  <active value="true" />
</Patient>
```

Figure 3.3 Patient information in XML format.

```
{
  "resourceType": "Medication",
  "name": "ENALAPRIL 5MG",
  "code": {
    "coding": [{
      "code": "10000001",
      "display": "ENALAPRIL 5MG (TABLET) - 1 TAB Once daily",
      "primary": false
    }]
  },
  "isBrand": false
}
```

```
{
  "resourceType": "Medication",
  "name": "ATENOLOL 25MG",
  "code": {
    "coding": [{
      "code": "10000002",
      "display": "ATENOLOL 25MG (TABLET) - 1 TAB Once Daily",
      "primary": false
    }]
  },
  "isBrand": false
}
```

```
{
  "resourceType": "Medication",
  "name": "ASPIRIN 81MG",
  "code": {
    "coding": [{
      "code": "10000003",
      "display": "ASPIRIN 81MG (TABLET) - 1 TAB Once daily"
      "primary": false
    }]
  },
  "isBrand": false
}
```

```
{
  "resourceType": "Medication",
  "name": "SIMVASTATIN 10MG",
  "code": {
    "coding": [{
      "code": "10000004",
      "display": "SIMVASTATIN 10MG (TABLET) - 1 TAB at bedtime
      "primary": false
    }]
  },
  "isBrand": false
}
```


Figure 3.4 The characteristics of medication resources to server.

```
<Medication xmlns="http://hl7.org/fhir">
  <name value="ENALAPRIL 5MG" />
  <code>
        <coding>
            <code value="10000001" />
            <display value="ENALAPRIL 5MG (TABLET) - 1 TAB Once Daily" />
            <primary value="false" />
        </coding>
    </code>
  <isBrand value="false" />
</Medication>
<Medication xmlns="http://hl7.org/fhir">
  <name value="ATENOLOL 25MG" />
  <code>
        <coding>
            <code value="10000002" />
            <display value="ATENOLOL 25MG (TABLET) - 1 TAB Once Daily" />
            <primary value="false" />
        </coding>
    </code>
  <isBrand value="false" />
</Medication>
<Medication xmlns="http://hl7.org/fhir">
  <name value="ASPIRIN 81MG" />
  <code>
        <coding>
            <code value="10000003" />
            <display value="ASPIRIN 81MG (TABLET) - 1 TAB Once Daily" />
            <primary value="false" />
        </coding>
    </code>
  <isBrand value="false" />
</Medication>
<Medication xmlns="http://hl7.org/fhir">
  <name value="SIMVASTATIN 10MG" />
  <code>
        <coding>
            <code value="10000004" />
            <display value="SIMVASTATIN 10MG (TABLET) - 1 TAB at bedtime" />
            <primary value="false" />
        </coding>
    </code>
  <isBrand value="false" />
</Medication>
```


Figure 3.5 Medication information taken from server in XML format.

3.3 Policy of medication refilling system

We design the policy and medication refilling system based on clinical practice in Thailand including the success refill clinics from literatures review [5], [19-21]. We adopt HL7 standard in data communication and application design. The schematic of system are shown as Figure 3.6.

3.3.1 Patients enrollment

Refill request by patient is desired. We set inclusion criteria with the stable condition of chronic outpatient allowance by physician.

Health condition that effects to communication skill such as psychiatric disease must be excluded. Patients have to sign the informed consent. The content of inform consent base on the Act for patient right. Patients must understand and accept the detail of consent form.

Content of the informed consent:

The informed consent is used for patient agreement to protect the unawareness. Patients must understand and accept. The detail must cover 3 major topics as follows:

a) Medication refill is not physician follow-up. However, after completion of medication refills with given duration, the patient must have a physician appointment.

b) Medical history including diagnostic diseases will be disclosed to pharmacists.

c) Medication brand name may be substituted base on the pharmaceutical equivalent, and pharmacist must explain to the patient.

3.3.2 Medications for refills

We do not allow any prohibited medication to refill, because these medications would cause the harmfulness and addiction. Prohibited medications depend on Thai FDA's law and regulation, including narcotics, opioid derivative, and other controlled substances such as sleeping pill [23-24]. Other serious medications such as warfarin and its derivatives (medication uses for preventing blood clot) are depended on physician’s judgments. Short course medication treatment is as follows.

The antibiotics should be complete at physician visit. Hospital pharmacist must verify all prescription before data is inputted to system.

Time allowance for prescription refill must not more than 6 months per prescription. After the completed prescription refilling, the patient must see the physician to evaluate the health condition in order to get the new prescription. Patient can request the reasonable duration for refilling, such as every month or every few months.

3.3.3 The pharmacy stores

The pharmacy store requires the Good Pharmacy Practice, accredited by The Pharmacy Council of Thailand. Medication refill service by accredited pharmacy store complies with Thailand NHSO's policy. The accredited pharmacy store ensures the quality pharmaceutical care service standard [27]. On the duty, the registered pharmacists, satisfying a medication refilling system's training course, are available for chronic patients with medication refill service. Pharmacists must take care of patients with code of pharmaceutical ethics to protect the patient's right.

3.3.4 Electronic data communication

With HL7 standard, the data exchange between hospital and pharmacy in XML format [10]. The information for a medication refilling system is divided into 2 parts. First is the demographic data, including national identification number (ID), hospital number (HN), name - surname, date of birth, age, sex, diagnostic disease and drug allergy (if known). Another part is refilling part, including prescription ID, medication list, visiting date, next appointment date, attending physician, amount of pills, and time of refilling. Underlying disease is the useful information for patient education and evaluation for the appropriate of drug use.

National ID is the best perform for linking data. This is because Thai people have their own unique ID, having one pattern for person identifier. On the other hand, the hospital number (HN), having various standards, is unsuitable for multiple facilities.

3.3.5 Application process design

3.3.5.1 Hospital process

After the process of patient enrollment has been already completed, Pharmacist verifies the prescription to ensure that the exceptional drug must be excluded.

a) Refill medication data is inputted into medication refilling system, whereas the refill medication ID is generated.

b) Other information is transferred to medication refilling system from Hospital Information System (HIS). National ID is used for linking information to system.

c) Medication refilling system generates the refill medication sheet to patient, including prescription refill ID, refill date, next physician appointment date, pharmacy contact details, and medication profile.

3.3.5.2 Pharmacy store process

After completion of information on system (on the next working day), the process can be described as follows:

a) With notification from system to pharmacy store, the pharmacy manages and prepares the available stock. If stock is not available, pharmacy has to contact the pharmaceutical companies for purchasing.

b) Three days before due date, the system will send the reminder message to pharmacist. Then, pharmacist will make a reminder call to patient.

c) Pharmacist should perform the patient counseling and education. On another hand, Pharmacist can take a note, if problems are occurred.

d) The refill data and log, being usable for hospital information system (HIS), are transferred back to system. Physician can monitor patient form the log data.

3.2.6 Others

We have the policy to control the medication price for pharmacy store by signing contract with medical dealers. Prize must as equal as selling to hospital.

Contracted laboratory center provides the data, which are transferred to system by request. Laboratory order and parameters are exchanged by HL7 messages. Laboratory data are useful for patient monitoring.

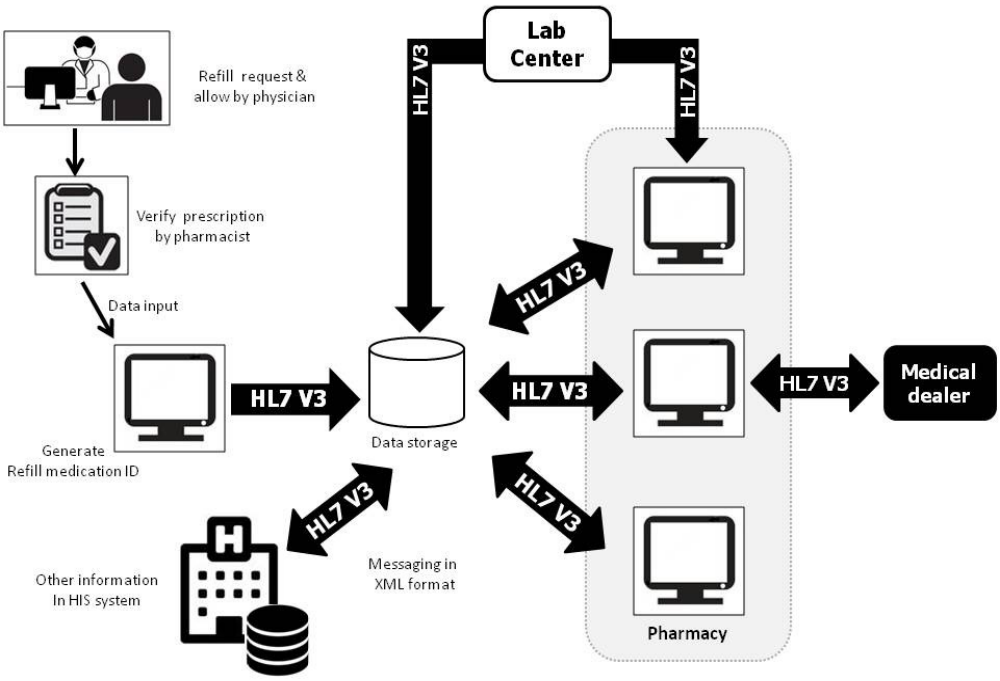

Figure 3.6 Illustration of schematic of system.

3.4 Key stakeholders' roles and responsibilities

We define key stakeholders in 2 categories given as: providers and customers. Providers deliver the medication refilling service to the customers and ensure the satisfaction. Customers receive the service from providers. The roles and responsibilities are as follow.

3.4.1 Providers

- Physicians treat, order the laboratory parameters, prescribe the medication for patient and give the permission of patient’s refill request.
- Hospital pharmacists verify the prescription, and input the medication data to the system.

- Community pharmacists, who work at the pharmacy stores provide the medication refill service, and give some pharmacy education/counseling.
- Laboratory center officers input/support the information request into the system.
- Medical dealers provide the medication to the pharmacy store with the price control. Medical dealer is vender of medication refill system and must comply with Vender Managed Inventory (VMI) of the Government Pharmaceutical Organization (GPO).

3.4.2 Customers

Patients request for refilling system, and choose the pharmacy store where those patients prefer.

3.5 A case study

Patient Mr.AB, Male 64 years old, Date of birth: 1 Jan 1950, HN 5736260, National ID. 1909800061237. He had underlying diseases which are hypertension and dyslipidemia. He got whole prescription for 3 months, and need to refill prescription every month. Prescription contained 5 medications, given as

1. Enalapril 5 mg 1 tab once daily,
2. Atenolol 25 mg 1 tab once daily,
3. Aspirin 81 mg 1 tab once daily,
4. Simvastatin 10 mg 1 tab at bedtime,
5. Alprazolam 0.5 mg 1 tab at bedtime for insomnia.

Hospital pharmacist verifies the prescription and excludes alprazolam, which is found to be the controlled substance. Solutions are prescribing whole amount of alprazolam at this hospital visit, or are changing to other that is not controlled substance.

Medication for refilling remains 4 items, given as:

1. Enalapril 5 mg 1 tab once daily,
2. Atenolol 25 mg 1 tab once daily,
3. Aspirin 81 mg 1 tab once daily,

4. Simvastatin 10 mg 1 tab at bedtime.

After verification step, prohibited medication must not be found in medication refilling system.

Trigger event is the refill request. Medication data and patient information are converted into *HL7 FHIR message*, and exchange data between hospital (sender) and pharmacy store (receiver). FHIR offers RESTful API to exchange resources via standard HTTP. We use *http://spark.furore.com/fhir* for testing server [12].

Creation procedures of patient information via RESTful API are shown in Figure 3.7. We use national ID number for linking the patient information. First step is POST which is the creation of new patient resources in server and requesting for information. Server responses to POST or requests by giving the location link. Then we GET or receive the patient information from the location link.

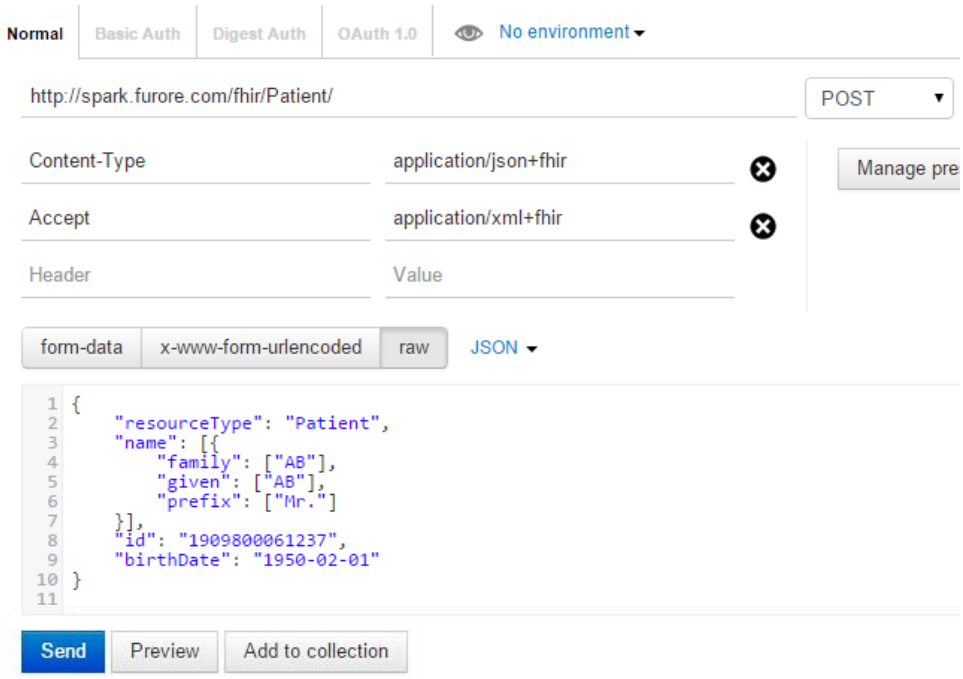

Figure 3.7a Illustration of the patient information's request for sending to the server.

Figure 3.7b Illustration of server responses with giving the location link.

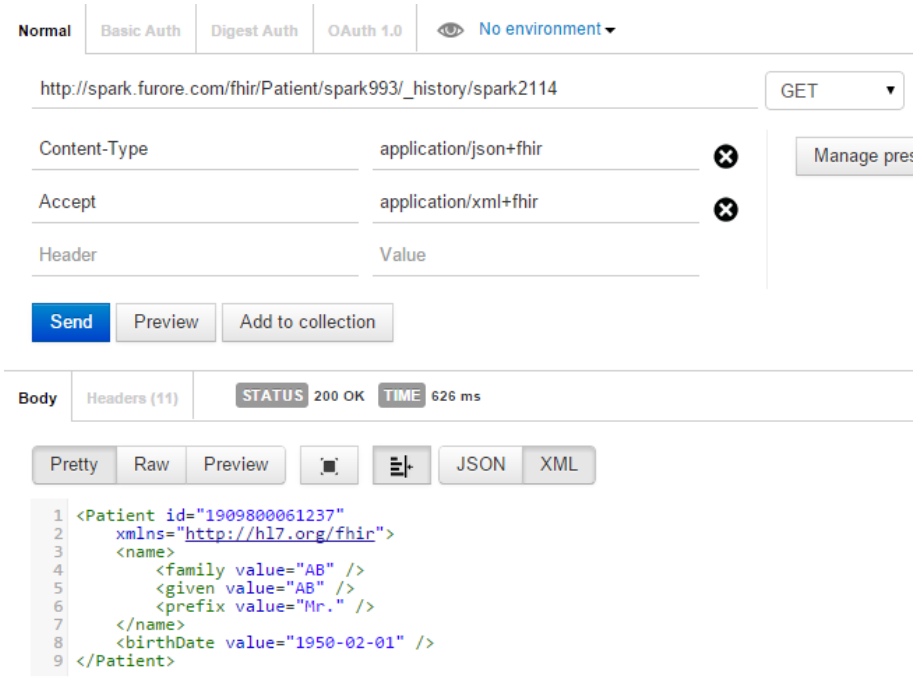

Figure 3.7c Illustration of getting the information with location link.

Figure 3.7 Procedure for creation of patient information via RESTful API.

3.6 Cost/time savings formulation scheme

According to the policy, we allow the patients to choose the convenient pharmacy stores. We can make assumption that patients will choose the pharmacy stores, located near their accommodations. It is clearly that the new policy outperforms the former policy in terms of lower transportation cost and time saving. Figure 3.8 shows the scenario of the pharmacy stores around the hospital. Moreover, the workload of physicians and hospital pharmacists shall be eliminated. This is because we share the workload to pharmacy stores for refilling prescription.

We develop the formulation of cost/time saving, including transportation cost, show in Eq. (3.1). Form Eq. (3.2), time saving, also includes the time spending for transportation and the waiting time between hospital and pharmacy store.

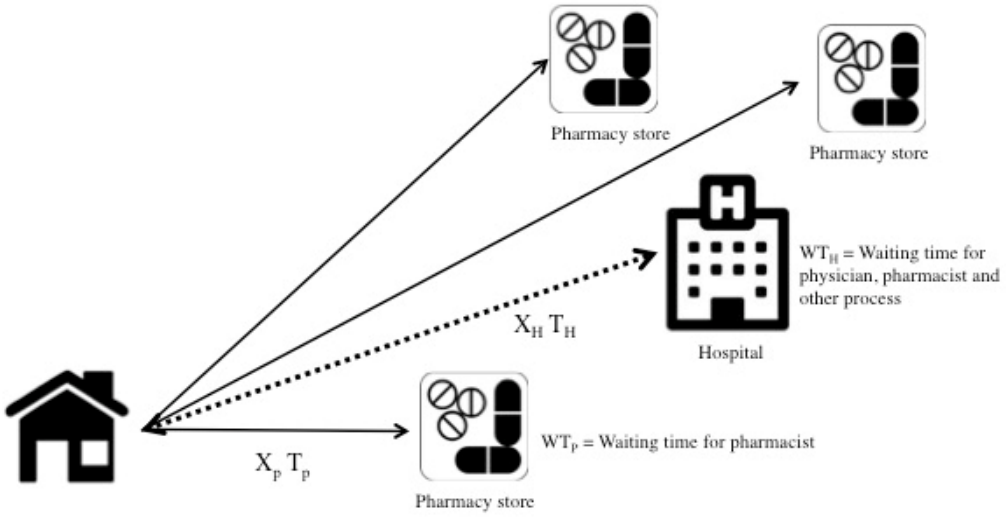

Figure 3.8 Scenario of pharmacy stores around hospital.

Assumption : $X_P < X_H$, $T_P < T_H$ and $WT_P < WT_H$

$$\text{Cost saving} = n(X_H - X_P). \tag{3.1}$$

$$\text{Time saving} = (T_H - T_P) + (WT_H - WT_P). \tag{3.2}$$

Where,

X_H = Cost of transportation form house to hospital;

X_P = Cost of transportation form house to pharmacy store;

T_H = Time for transportation form house to hospital;

T_P = Time for transportation form house to pharmacy store;

WT_H	=	Waiting time at hospital;
WT_P	=	Waiting time at pharmacy store;
n	=	Number of transportation.

To prove our assumption with cost/time saving formulation, we have randomly collected data about time and cost from a big hospital in Bangkok. We have collected waiting time for physician and medication. Time spent per prescription has been collected from accredited pharmacy store nearby the hospital. We have limited area of survey within Thonburi district. Unit of cost is Thai baht (THB) and unit of time is minute.

3.7 A survey method

After demonstrating the medication refilling system and representing the policy, we have developed the survey questionnaire to measure the perspectives of the policy. The questionnaire focuses on acceptability, accuracy, efficacy, applicability and satisfaction [5], [21]. Five-point scales (e.g., strongly disagree, disagree, neutral, agree and strongly agree) are used for answering [28]. We concentrate the efficacy in aspect of cost/time saving. Target groups are the key stakeholders, which are physicians, pharmacists, and chronic disease patients in Thailand. We have used *Taro Yamane* method to estimate the sample size. The estimated sample size of 400 is required for generating the 95% confidence level with ± 5% of margin of error [29].

Table 3.1 The survey questionnaire.

	Questionnaire
1	Do you accept or agree with medication refilling system?
2	Do you think that medication refilling system should be implemented in Thailand health system?
3	Do you satisfy the medication refilling system policy?
4	Do you think medication refilling system is possibly implemented in Thailand health system?
5	Suppose the medication refilling system has been implemented. Do you think this system improve the efficacy of medical service?
6	Suppose the medication refilling system has been implemented. Do you think this system reduce the workload of healthcare staff in hospital?
7	Suppose the medication refilling system has been implemented. Do you agree with this system share the patients and workload from hospital to pharmacy store?
8	Suppose the medication refilling system has been implemented. Do you think this system can save the patients costs comparing with current system (without medication refills)?
9	Suppose the medication refilling system has been implemented. Do you believe in accuracy of information?

CHAPTER IV
RESULTS AND DISCUSSIONS

In this chapter, we demonstrate the results of communication via HL7 FHIR Restful protocol from our case study. We demonstrate the results of cost/time saving formulation by scenario and data collection. The survey results show the characteristics of responders and descriptive statistic in each topic.

4.1 A case study

We have proved our assumption of exchanging health information with HL7 concept. HL7 FHIR testing server is used for data storage as HIS. After completed the patient enrollment and verification step, the prescriptions data is inputted to the server. Related patient information is received from HIS. Both prescription and patient information are converted into *HL7 FHIR message* with XML format. We customize the XML schema from FHIR's resources. Information is exchanged between hospital and pharmacy store via RESTful over HTTP.

Prescription:

1. Enalapril 5 mg 1 tab once daily,
2. Atenolol 25 mg 1 tab once daily,
3. Aspirin 81 mg 1 tab once daily,
4. Simvastatin 10 mg 1 tab at bedtime.

The prescription is translated to HL7 messages, because the prescription is current and updates information. Status is active for ongoing process in medication refilling system at that time. HL7 messages for this case study are shown in Figure 4.1.

```
<MedicationPrescription xmlns="http://hl7.org/fhir">
  <dateWritten value="2015-04-17" />
  <status value="active" />
  <patient>
    <reference value="Patient/spark44" />
    <display value="Roel" />
  </patient>
  <prescriber>
    <reference value="Practitioner/f002" />
  </prescriber>
  <medication>
    <reference value="Medication/spark6" />
    <display value="ENALAPRIL" />
  </medication>
  <dosageInstruction>
    <text value="ENALAPRIL 5MG" />
    <method>
      <coding>
        <code value="10000001" />
        <display value="ENALAPRIL 5MG (TABLET) - 1 TAB Once Daily" />
      </coding>
    </method>
  </dosageInstruction>
</MedicationPrescription>
```

```
<MedicationPrescription xmlns="http://hl7.org/fhir">
  <dateWritten value="2015-04-17" />
  <status value="active" />
  <patient>
    <reference value="Patient/spark44" />
    <display value="Roel" />
  </patient>
  <prescriber>
    <reference value="Practitioner/f002" />
  </prescriber>
  <medication>
    <reference value="Medication/spark7" />
    <display value="ATENOLOL" />
  </medication>
  <dosageInstruction>
    <text value="ATENOLOL 25MG" />
    <method>
      <coding>
        <code value="10000002" />
        <display value="ATENOLOL 25MG (TABLET) - 1 TAB Once Daily" />
      </coding>
    </method>
  </dosageInstruction>
</MedicationPrescription>
```

```
<MedicationPrescription xmlns="http://hl7.org/fhir">
  <dateWritten value="2015-04-17" />
  <status value="active" />
  <patient>
    <reference value="Patient/spark44" />
    <display value="Roel" />
  </patient>
  <prescriber>
    <reference value="Practitioner/f002" />
  </prescriber>
  <medication>
    <reference value="Medication/spark8" />
    <display value="ASPIRIN" />
  </medication>
  <dosageInstruction>
    <text value="ASPIRIN 81MG" />
    <method>
      <coding>
        <code value="10000003" />
        <display value="ASPIRIN 81MG (TABLET) - 1 TAB Once Daily" />
      </coding>
    </method>
  </dosageInstruction>
</MedicationPrescription>
```

```
<MedicationPrescription xmlns="http://hl7.org/fhir">
  <dateWritten value="2015-04-17" />
  <status value="active" />
  <patient>
    <reference value="Patient/spark44" />
    <display value="Roel" />
  </patient>
  <prescriber>
    <reference value="Practitioner/f002" />
  </prescriber>
  <medication>
    <reference value="Medication/spark9" />
    <display value="SIMVASTATIN" />
  </medication>
  <dosageInstruction>
    <text value="SIMVASTATIN 10MG" />
    <method>
      <coding>
        <code value="10000004" />
        <display value="SIMVASTATIN 10MG (TABLET) - 1 TAB at Bedtime" />
      </coding>
    </method>
  </dosageInstruction>
</MedicationPrescription>
```

Figure 4.1 HL7 messages format with the prescription data.

4.2 A cost/time saving formulation

4.2.1 The cost/time saving scenario

The scenario: Patient's house is far 2.1 Kilometers from pharmacy store. Hospital is far from house 5.3 Kilometers.

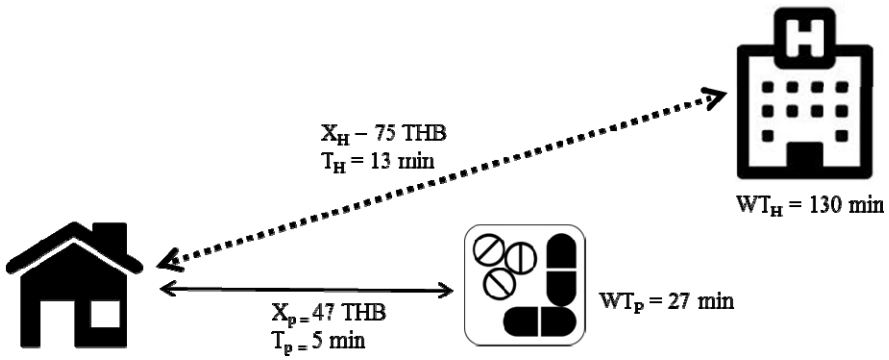

Figure 4.2 Scenario of cost/time saving.

At pharmacy store, pharmacist's spending time per prescription is about 27 minute, including preparing and dispensing time. A transportation cost by taxi is 47 THB and take about 5 minute without traffic jam.

At hospital, time spending for physician, including waiting time and physical examination time is about 55 minutes. A pharmacy waiting time is about 75 minutes. Time spent for hospital process is totally 130 minutes. A transportation cost by taxi is 75 THB and take about 13 minutes without traffic jam.

$$\text{Cost saving} = n(X_H - X_P) \quad (3.1)$$

$$= 2(75 - 47) \quad ; \text{n = 2 (for round trip)}$$

$$= 56 \text{ THB}$$

$$\text{Time saving} = (T_H - T_P) + (WT_H - WT_P) \quad (3.2)$$

$$= (13 - 5) + (130 - 27)$$

$$= 111 \text{ minutes}$$

For this scenario, from Eq. (3.1) - (3.2), we can save cost for 56 THB and time for 111 minutes per a refill prescription. But this scenario, the prescription is for 3 months and patient requests to refill every month. Patient has to refill 3 times to complete this prescription. Therefore, we can calculate total cost/time saving as follows.

Cost saving:	56 x 3	= 168 THB.
Time saving:	111 x 3	= 333 minutes.

4.2.2 Cost/time saving data collection

We collected data by interview method. The patients and pharmacists have been interviewed. Time and cost for transportation are estimated by interviewing patient. Some patients have taken by taxi but the others have taken by public bus.

We have gathered waiting time for physician and dispensing at hospital. Waiting time at pharmacy stores was estimated by interviewing pharmacists. We give example of prescriptions to pharmacists, and pharmacists prepare the medication for patients. The processes include preparing medication and dispensing time. All processes time is collected.

Table 4.1 Time data collection for time saving calculation.

	No. of Med. (items)	Time for transportation		Waiting time		Time saving (min)	% of time saving
		Hospital (min)	Pharmacy store (min)	Hospital (min)	Pharmacy store (min)		
1	5	13	5	130	27	111	77.6
2	7	60	15	95	30	110	70.9
3	3	20	5	60	15	60	75
4	6	25	10	65	18	62	58.1
5	8	30	15	95	22	88	70.4
6	5	45	10	90	24	101	74.8
7	4	15	5	85	21	74	74
8	10	55	25	135	39	126	66.3
9	9	40	30	100	35	75	53.6
10	12	30	10	125	42	103	66.5
Total time saving						910	68.7

Table 4.2 Cost data collection for cost saving calculation.

	No. of Med. (items)	Cost for transportation		Cost saving (THB)		% of cost saving
		Hospital (THB)	Pharmacy store (THB)	n = 1; one way (THB)	n = 2; round trip (THB)	
1	5	75	47	28	56	37.3
2*	7	22	9	13	26	59.1
3	3	50	37	13	26	26
4	6	45	40	5	10	11.1
5	8	75	50	25	25	16.7
6	5	15	10	5	10	33.3
7*	4	18	9	9	18	50
8*	10	9	9	0	0	0
9	9	80	45	35	70	43.8
10	12	50	39	11	22	22
Total cost saving					263	29.9

*Case no.2, 7, 8 transported by bus, the rest transported by taxi.

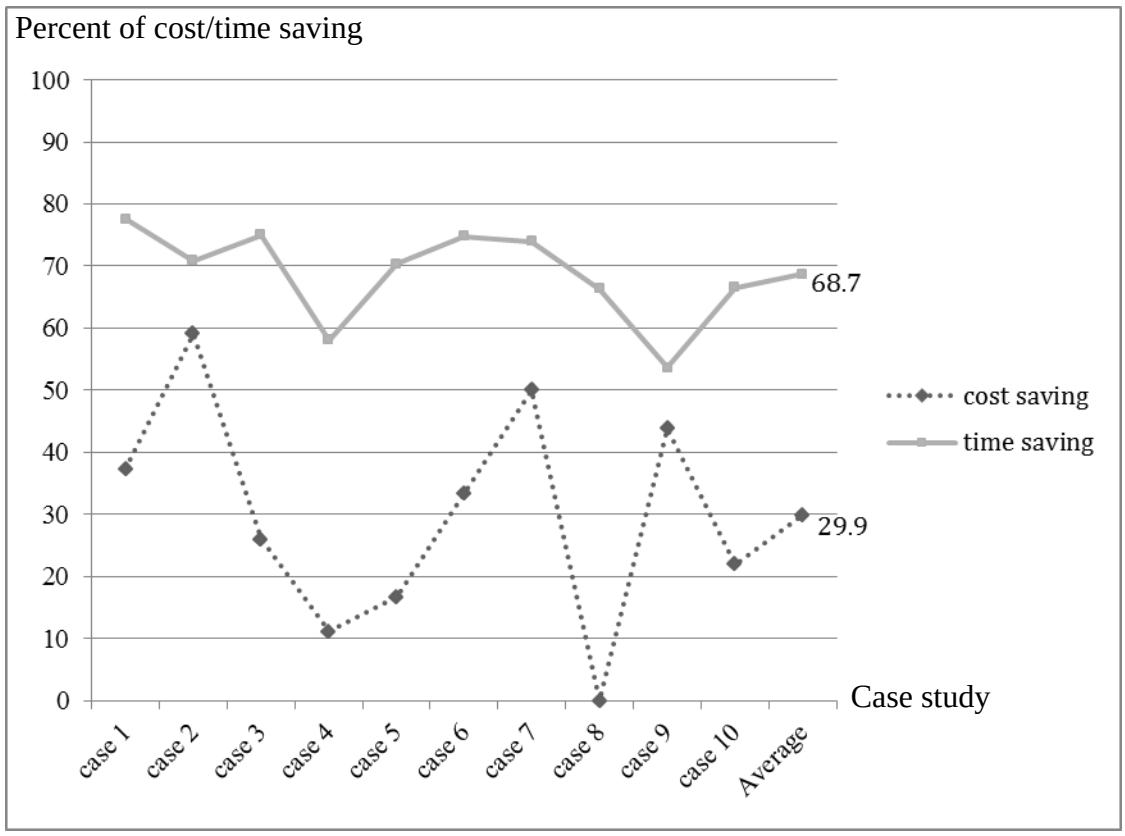

Figure 4.3 The percent of cost saving shown in dot line and the percent of time saving shown in gray line.

It can be summarized that we can save time for 910 min, and cost for 263 THB per 10 cases (average time saving is about 91 minutes/case, and cost saving is about 26.3 THB/case). The average percentage of cost and time saving are 29.9 and 68.7, respectively. (shown in Figure 4.3) By the results, we have noticed the waiting time at pharmacy store depending on number of medications. However, hospital waiting time does not depend on the number of medications, it influenced by many factors, given as: the number of crowded patients, the number of on-service-physicians, time spent in other processes, and so on. Another factor related is the transportation method. In some case, medication refilling system does not save cost however, the waiting time for their medications are reduced.

4.3 Results of survey

In data survey, with the responding questionnaire by 130 persons (90% confidence level with ± 10% of margin of error), the responders consist of 39 physicians (30%), 54 pharmacists (42%) and 37 patients (28%).

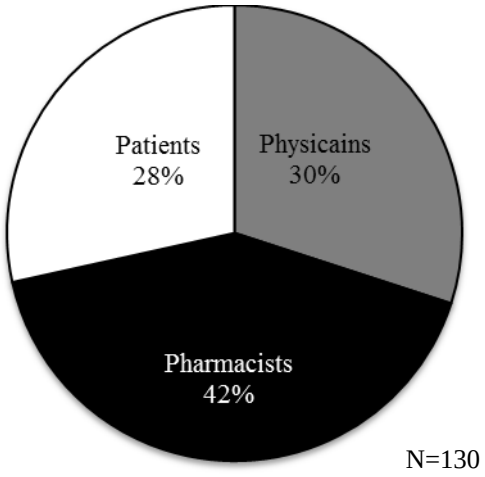

Figure 4.4 Percentage of responders.

Table 4.3 Results and descriptive statistics.

	Acceptability		Efficacy		Accuracy		Applicability		Satisfaction	
	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD
Physician	3.82	1.1	3.78	1.09	3.87	1.24	3.05	0.92	3.62	1.04
Pharmacist	4.07	0.82	3.90	0.90	3.87	0.91	3.11	0.95	3.78	0.74
Patient	4.20	0.78	4.07	0.69	4.03	0.80	3.57	0.80	3.92	0.72
Total	4.03	0.91	3.92	0.91	3.91	0.98	3.22	0.92	3.77	0.84

mean = average scales of the questionnaire's answers that maximum scale are five, and SD = standard deviation.

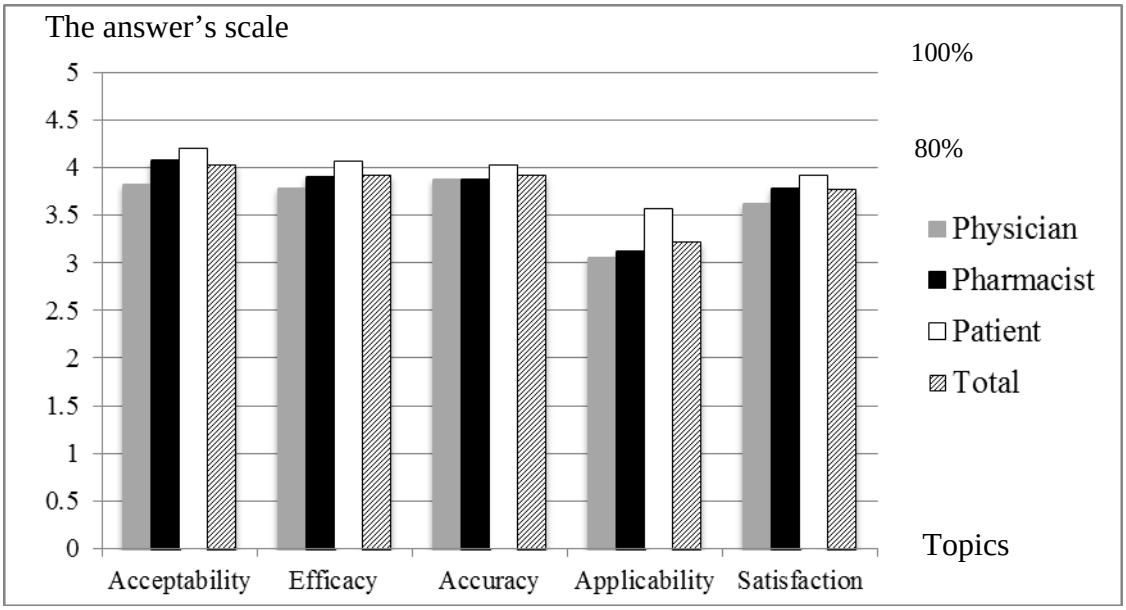

Figure 4.5 Comparison of survey results in each topic.

It is shown that policy acceptability is 80% of total's answer scale, and policy satisfaction is 75.4%. The 78.2% of responders expect the accuracy of system in data exchange. The 78.4% believe that policy can provide the effectiveness of medication refilling system resulting in time and cost saving. The 64.4% agree with the policy and should be implemented. Patients are the highest acceptant score comparing with pharmacists and physician by the score of 4.20, 4.07, and 3.82, respectively. Patients also give the highest score in the rest topics which are efficacy, accuracy, applicability, and satisfaction, although physicians give the lowest score in every topic. The possible reason is medication refills service improves patient's convenience. The lowest score is policy applicability from physicians (3.05). This is because those physicians do not believe in the policy effect. Some physicians give criticize that patient can easily loss the follow-up with the medication refill service. Physicians concern about patient safety, if pharmacists handle the management. With this concern, we ensure the quality of pharmaceutical service by accredited pharmacy.

4.4 Discussions

Our assumption about cost and time saving benefit is true supporting by the results. Medication refilling system can save more cost and time than current health system (without medication refilled).

According to time saving, stakeholders (physicians and pharmacists) believe that medication refilling system could eliminate the old chronic patients' hospital visits, and also reduce the hospital staffs' workload. The rush hours should reduce. For this point, we can assume that hospital's service quality would be improved especially outpatient service. Hospital can serve the new patient more efficiency. Patient education is another advantage and increase patient's the awareness. This is because the hospital pharmacists, handling the complex responsibility and community pharmacist at pharmacy store, can perform efficiency for drug counseling without interruption by other workload. The pharmacy store can give flexible service time for the refill, not limit for official working hours.

The data collection of cost/time saving are used for proving the formulation and our assumption. It may not represent the general population.

Most of stakeholders accept and satisfy the policy and system. However, some stakeholders still concern about data accuracy and privacy. The convenient of the medication refilling system is the major reason that made patients preferred. Some physicians concern about pharmacist's performance and patients who are easily to loss the follow-up. Another importance factor is aligning with national health policy which can prevent conflict between stakeholders. Impact analysis of policy should perform to get rid of concerning about policy's effect. The new policy must design to comply with the related law and regulation. Defining key stakeholders and making the stakeholders understands benefits are important. Integration of medical knowledge, pharmaceutical knowledge and technology need for successful of electronic refill medication policy. Sustainability is considered for the continuous improvement.

HL7 messages are effective standard for medication refilling system. For the first step, setting goal is recommended. The second step is data understanding, which includes the data structure and the importance information for system. The third is the suitable standard selection because there are severally HL7 specifications with

difference objectives. Medication refill processes are essential for system design. Finally, we can implement the HL7 standard with the medication refill service.

Using HL7 standard is tools for implementation. HL7 promotes the data communications seamlessly, and enhances the system efficiency. Messages can share between client and server via network. Our case study with FHIR exchanges the resources via standard HTTP. It is proved that data exchanges are accurate. HL7 message can exchange in the real time processes. FHIR resources are appropriate for implementer, because of flexibility and manageability. HL7 standard should apply in other health informatics system and achieves interoperability among healthcare facilities.

4.5 Limitations

These cost/time saving results are shown the data based on patient's perspective. We do not include cost/time from other processes, given as: patient registering, nursing, lab monitoring, etc. For more precise results, we should include every hospital process time and wages of healthcare staffs in further study. Moreover, chronic disease patients usually visit hospital with the care givers. Medication refill service can save care giver’s time and cost.

In the survey for large population, 400 sample sizes are required to create 95% confidence level ± 5% of margin of error and standard normal distribution. We have too small responders and generate 90% confidence level ± 10% of margin of error because we have limited of survey time.

The responders consist of physicians and pharmacists in operational level. We do not include the executive board in the survey. The policy makers or executive boards are decision makers for implementation. The major of Thai health system operates by governance. The governance is the policy maker and concern about overall benefit from hospital. Medication refilling system share patients form hospital to pharmacy store that means reducing hospital’s benefit. Win-win situation between hospital and pharmacy store can convince the policy maker to allocate expenditure for the system. Making contract with the pharmacy store may be the solution to control the benefit.

For implementing the new policy, there are multidimensional involved. We recommend identifying the decision maker as a first priority. The policy makers concern about total national healthcare expenditure. The expenditure covers all cost from healthcare processes and related activities. The medication refill service must prove the cost benefit, not only the quality of system. The cost is divided into medication cost, fee, service charge, staff's wages and other indirect cost. Indirect cost can be time, better clinical outcome and quality of life. Cost effectiveness analysis can clarify the problem.

In real situation, the stakeholders involved in the medication refill services are not only physicians, pharmacists and patients. Other stakeholders may be nurses, physician's assistants, healthcare staffs, and hospital's officers. All stakeholders must be clarified in further study.

Other solution which not reduced hospital's benefit may be considered. For example, the hospital initiates refill service by post.

Infrastructure of the system is not mentioned in this study. We have to plan the infrastructure specifications and its cost before the real implementation. Application development is next step. Requirement analysis should be done. System security is another concern for protecting patient's privacy. Hypertext Transfer Protocol Secure (HTTPS) may be used. Authentication and access control must be raised in security policy.

CHAPTER V
CONCLUSIONS

This research demonstrates the benefits of medication refill policy between hospital and pharmacy. Medication refilling system provides the convenience for stakeholder especially for patients. The benefit of medication refilling system is also sharing the patients and workload from hospital to pharmacy stores. In the same way, medication refills service could enhance the performance of the community pharmacy. Implementation of healthcare standard can improve the quality of medication refill service. Exchanging electronic health information exchange standard is key solution for interoperability between hospital and pharmacy stores. HL7 is a good standard for the electronic medication refilling system to communicate data. Resources, provided by FHIR, are the effective framework for implementation of HL7 concept.

Although, medication refill policy is not in Thailand's health standard. It is a challenge to implement the new policy. It is not easy to change the habit of Thai people. In this research, we try to integrate the medication refill policy with the information system to ensure the system quality. Policy makers should review the problems and find their solutions. With the results of low transportation cost and time saving, the system makes stakeholder satisfaction and acceptability.

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